## **CLAIMS**

1. Immediate-release pharmaceutical or nutraceutical micronized powder having a particle size of at most 100 µm and comprising the combination of at least one active substance, at least one wetting agent and at least one diluent.

5

35

- 2. Powder according to Claim 1, characterized in that it has a particle size of at most 50  $\mu m$ .
  - 3. Powder according to Claim 1, characterized in that it has a particle size of at most 10  $\mu m$ .
- 15 4. Powder according to any one of Claims 1 to 3, characterized in that it allows the dissolution of all of the active substance(s) in less than 30 seconds, when it is administered mucosally.
- 20 5. Powder according to any one of Claims 1 to 4, characterized in that the active substance is in a micronized form.
- Powder according to any one of Claims 1 to 5, 6. characterized in that the active substance 25 selected from the group consisting of cyproterone acetate, norethisterone acetate, progesterone, keto-desogestrel, norgestimate, laevonorgestrel, desogestrel, gestodene, natural estrogens such as 30 estradiol and derivatives thereof, synthetic ethinylestradiol, estrogens such as androstenedione, testosterone, dihydrotestosterone trinitrine, androstanolone, DHEA, fentanyl, S(-)), nicotine (nicotine nitroglycerine,

dinitrate,

isosorbide

scopolamine, clonidine,

alclometasone dipropionate, phloroglucinol, molsidomine, acetazolamide, acyclovir, adapalene, alclomethasone dipropionate, amcinonide, ameline, bamethan sulphate + escin, betamethasone valerate, 5 betamethasone dipropionate, bufexamac, caffeine, calcipotriol monohydrate, cetrimonium bromide, clobetasol crilanomer, propionate, desonide, dexpanthenol, diclofenac, diflucortolone, valerate, difluprednate, diphenydramine hydrochloride, 10 econazole nitrate, erythromicin, flumetasone pivalate, fluocinolone acetonide, fluocinodine, fluocortolone fluocortolone, hexanoate, fluocortolone pivalate, hydrocortisone, ibacitabine, hydrocortisone acetate, ibuprofen, 15 imiquimod, ketoconazole, ketoprofen, lidocaine, metronidazole, miconazole nitrate, minoxidil, nifluminic acid, penciclovir, benzoyl peroxide, iodinated povidone, promestriene, piroxam, pyrazinobutazone, roxithromycin, sulphacetamide, 20 triamcinolone, tazarotene, tretinoin and isotretinoin, triclocarban, vidarabine β-3-adrenergic agonist, growth monophosphate, buprenorphine, pergolide, hormone, oxybutinin,  $7\alpha$ -methyl-19-nortesterone, nestorone, mecamylamine, salbutamol, clenbuterol, selegiline, 25 lidocaine, ketorolac, buspirone, ketotifen, insulin,  $\alpha$ -interferon, prostaglandins, eptazocine, 5-aminolevulinic acid, benzodiazepine alprozolam, flubiprofen, ketoprofen, diclofenac, fenoprofen, phenidate, miconazole, 30 piroxicam, methyl alprozolam, dexmedetomidine, bruprenorphine, antagonist), alprostadil, (α-adrenergic prazosin ethinyl (β-adrenergic agonist), tulobuterol norelgestromin, ketorolac, oestradiol physostigmine, medindolol ( $\alpha$ -adrenergic agonist), 35

rotigotine (dopamine D2 antagonist), thiatolserine, Esomeprazole, Melagatran (in the case of thrombosis), Rosuvastatin, Ezetimide, Pitavastatin (hyperlipidaemia), Mitiglinide (type II diabetes), (asthma), Aripipazole Cilomilast, Viozan (psychiatry), Omapatrilat (hypertensive), (cancerology), Caspofongin acetate, Voriconazole (infections), new COX inhibitors such as Etoricoxib (inflammation), Valdecoxib (arthritis) Substance P antagonist (depression), Parecoxib, Darifenacin (urology), Eletriptan (migraine), Alosetron, Tegaserod, Capravirine (HIV), Finasteride inhibitor) and combinations (5-alpha reductase thereof.

15

10

5

7. Powder according to any one of Claims 1 to 6, characterized in that the active substance(s) is (are) selected from the group comprising vitamins, inorganic salts, and brewer's yeast.

20

25

- 8. Powder according to any one of Claims 1 to 7, characterized in that the wetting agent is selected from polyols such as sorbitol, or glycerin, PEG, hexylene glycol, triacetin, hydrogenated vegetable oils such as hydrogenated castor oil, polyoxy(ethylene)polyoxy(propylene) copolymers such as Lutrol® F68, polyoxyethylene alkyl ethers such as the Cremophor®, and mixtures thereof.
- Use of a powder according to any one of Claims 1 to 30 9. 8, characterized in that the diluent is selected from the group consisting of calcium or sodium or bicarbonate, sucrose, mannitol, carbonate lactose, maltotol, glucose, xylitol, sorbitol, 35 cellulose or microcrystalline cellulose powder,

starch and its derivatives, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulphate, dextrates, dextrins, dextrose excipients, fructose, kaolin, lactitol and mixtures thereof.

5

- 10. Powder according to any one of Claims 1 to 9, characterized in that it further comprises an antistatic agent.
- 10 11. Powder according to Claim 10, characterized in that the antistatic agent is selected from the group consisting of colloidal silica, magnesium silicate, talc, calcium silicate and tribasic calcium phosphate and mixtures thereof.

15

12. Powder according to any one of Claims 1 to 11, characterized in that it further comprises a binder which may be selected from the group consisting of acacia, alginic acid, carboxymethyl cellulose sodium, microcrystalline cellulose, dextrins, ethyl cellulose, gelatin, glucose, guar gum, hydroxypropyl methyl cellulose, methyl cellulose, polyethylene oxide, povidone, pregelatinized starch and mixtures thereof.

25

Powder according to any one of Claims 1 to 12, 13. it further comprises characterized in that absorption enhancer selected from the consisting of aliphatic fatty acid esters such as 30 isopropyl myristate, fatty acids such as oleic acid; alcohols or polyols, such as ethanol, propylene glycol and polyethylene glycol; the components of essential oils and terpen derivatives (such menthol); eugenol, geraniol, nerol, eucalyptol, surfactants, preferably non ionic, such as 35

polyoxyethylene sorbitan (fatty acid polyoxyethylene alkyl ether, polyoxyethylene derived from castor oil; moisturizers such as glycerin, urea; keratolytic agents, such as alpha-hydroxy acids (lactic acid, citric acid, etc), 23-lauryl ether, aprotinin, azone, benzalkonium chloride, cetylpyridinium chloride, cetyltrimethylammonium bromide, cyclodextrins, dextran sulphate, lysophosphatidylcholine, menthol. methoxysalicylate, methyl oleate, oleic acid, phosphatidylcholine, polyoxyethylene, polysorbate EDTA, sodium glycocholate, 80, sodium sodium glycodeoxycholate, sodium lauryl sulphate, sodium sodium sodium taurocholate, salicylate, taurodeoxycholate, sulphoxides, alkyl glycosides and mixture thereof.

- 14. Powder according to any one of Claims 1 to 13, characterized in that it further comprises an edulcorant agent and/or a flavoring agent.
  - 15. Powder according to Claim 14, characterized in that the edulcorant agent is selected from the group consisting of aspartam, dextrates, dextrose, fructose, mannitol, sodium or calcium saccharinate, sorbitol, sucralose, sucrose, and mixtures thereof.
- 16. Powder according to Claim 14, characterized in that the flavoring agent is selected from the group consisting of flavors of synthetic, semi-synthetic or natural origin, such as for example mint, peppermint, lemon, banana, strawberry, raspberry, mandarin, orange, vanilla, passion fruit, caramel, and the mixtures thereof.

25

5

10

15

17. Powder according to any one of Claims 1 to 16, characterized in that it is in a form suitable for its application on the buccal mucosa, the nasal mucosa or the vaginal mucosa.

5

- 18. Powder according to any one of Claims 1 to 14 characterized in that it is in a form suitable for its application to the buccal mucosa sublingually.
- 10 19. Powder according to any one of Claims 1 to 18, characterized in that it is in a sprayable form.
- 20. Powder according to any one of Claims 1 to 18, characterized in that it is packaged in a single-dose packet.
  - 21. Powder according to any one of Claims 1 to 18, characterized in that it is packaged in a thermally moulded capsule provided with a peelable operculum.

20

22. Powder according to any one of Claims 1 to 18, characterized in that it is in a packaging suitable for powder administration known to those skilled in the art.

25

23. Use of a powder according to any one of Claims 1 to 20, for making a immediate-release pharmaceutical or nutraceutical composition.